

Application Serial No. 10/676,408
Filed October 1, 2003
Response dated December 4, 2006
Reply to Office Action mailed August 29, 2006
Atty. Docket: PEDI-13

REMARKS

Following this response, claims 1-51 are pending in this application.

Claims 1-50 presently stand rejected. Claims 1, 4, 12, 19, 27, 37, 41, 43, and 47 are presently amended. New claim 51 has been added. In view of these amendments and the discussion below, it is submitted that the application is now in condition for allowance.

Claim Rejections 35 U.S.C. § 102

The Examiner has rejected claims 1-50 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,223,264 (Wehling). The Examiner states that Wehling discloses a method of administering an effervescent tablet for children comprising a pharmaceutically acceptable medicament contained within an aqueous dissolvable solid matrix. The Examiner has further rejected claims 1-26 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,261,601 (Talwar). In particular, the Examiner states that Talwar discloses the pharmaceutical composition of the drug and that the amount of drug to be used in the composition is that which is typically administered for a given period of time. In view of the amendments to the claims, Applicants disagree with the rejections over both Wehling and Talwar.

Applicants note that each of independent claims 1, 19, 27, 37, 41, and 47 (i.e., all independent claims) have been rejected as anticipated by one or both of Wehling and/or Talwar. In view of the present amendments to each of independent

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claims 1, 19, 27, 37, 41, and 47, Applicants respectfully disagree. In particular, Applicants note that the independent claims have been amended to recite a "gas-dispersing component" that includes a dissolvable solid matrix having at least one first gas contained therein. Support for this amendment can be found at least at paragraph [0024] of the present application, which describes that gas-dispersing components may be produced by dispersing the gas within a suitable medium, and then solidifying the medium to form a bubble, which contains or "entraps" the gas therein. While both Wehling and Talwar disclose tablets that can be orally administered (such as to pediatric patients) to delivery a medicament contained therein, neither Wehling nor Talwar discloses the particularly claimed solid matrix having a cavity therein containing a gas. Rather, Wehling and Talwar only describe standard tablet forms (prepared from granulations), which do not include gas-containing cavities such as are recited in the presently amended claims. Further, the present claims also recite a gas-generating effervescent component in addition to the gas-dispersing component. Such a combination of gas-dispersing and gas-generating components is not shown by either Wehling or Talwar. In view of the above, Applicants respectfully request a withdrawal of the rejections under 35 U.S.C. § 102(b) over both Wehling and Talwar.

Claim Rejections 35 U.S.C. § 112

The Examiner has rejected claim 12 under 35 U.S.C. § 112, first paragraph, stating that the specification, while being enabling for various inert gases

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such as carbon dioxide, nitrogen, air, helium, and oxygen, which the Examiner states can be treated as harmless in nature, does not reasonably provide enablement for ethylene oxide gas as broadly claimed in claim 12, which the Examiner asserts to be toxic. In response, Applicants have amended claim 12 to remove the reference to ethylene oxide. Thus, it is believed that the rejection of claim 12 under 35 U.S.C. § 112, first paragraph, is rendered moot.

However, Applicants have presently amended the claims to add new claim 51, which recites that the first gas of the composition may be ethylene oxide gas.

Applicants assert that ethylene oxide is an inert gas, just like nitrogen, air, etc., and thus the description thereof in the present specification is enabling therefore (regardless of the Examiner's assertion of toxicity).

Conclusion

For the foregoing reasons, it is submitted that all claims are patentable, and a Notice of Allowance is respectfully requested.

Please consider this paper to be a Petition for an Extension of Time of one month. A fee of \$60.00 is believed due as a result of this Petition. Any deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

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